

**REMARKS**

After amendment, claims 1-3, 14-19 and 35-40 remain pending in the present application. Claims 4-13 and 20-34 have been canceled *without prejudice* pursuant to the Examiner's restriction requirement and Applicant's election of invention. Previously presented claim 36 had been added to reflect the chemical species elected in response to the restriction requirement. Claims 37-40 provide further claims which read on the elected species. No new matter has been added by way of the present amendment. No new matter has been added by way of the present amendment.

Applicants note that any claim or subject matter which has been canceled from the previously pending claims is canceled *without prejudice* and Applicants reserve the right to pursue and prosecute any such subject matter in any one or more divisional applications at Applicants' discretion.

The Examiner has rejected the previously pending claims under 35 U.S.C. §103 for the reasons which were set forth in the May 2010 office action on pages 2-5 and were further confirmed in her November 18, 2010 Advisory Action. Applicants have reviewed the prior art cited against the presently claimed invention and carefully considered the Examiners' arguments. Applicants respectfully traverse the Examiner's rejection for the reasons which are presented herein, noting that the cited prior art Rogers, et al., US Patent No. 6,313,115 (Rogers) does not provide any disclosure whatsoever which credibly supports the Examiner's argument that the presently claimed invention is obvious. Applicants respectfully submit that, prior to the present invention, cognitive deficit associated with Sleep Deprivation and Stress was not known to be modulated through AMPAkine receptors and the use of AMPAkines to treat cognitive deficit due to sleep deprivation and/or stress was simply not in the prior art teachings.

In making her rejection of the presently claimed invention, the Examiner contends that Rogers teaches the elected compound 4-(benzofurazan-5-ylcarbonyl)morpholine and indicates that this compound is useful for alleviating impairment of memory or other

cognitive functions, brought on by a deficiency in the number or strength of excitatory synapses or in the number of AMPA receptors and further that treatment can be in humans, domesticated animals and laboratory animals. The Examiner further notes that Rogers does not expressly teach the acute or chronic sleep deprivation as a cause of cognitive impairment and the specified patient populations set forth in claims 16-19. Applicants wish to point out that that supposition is precisely Applicant's point and Applicant further notes that the present invention is non-obvious based upon that supposition. One of ordinary skill could not know or expect that AMPAkines would find use in treating cognitive deficit associated with sleep deprivation when no connection between cognitive deficit in sleep deprivation had been made in the art prior to the present invention.

Notwithstanding the fact that Rogers does not disclose or teach acute or chronic sleep deprivation as a cause of cognitive impairment, she nonetheless asserts that the teachings of Rogers render the present invention obvious. Applicants respectfully traverse both the Examiner's characterization of Rogers and the rejection of the instant claims on the basis of the disclosure therein.

Essentially, the examiner makes the assertion on p.3 that Rogers is prior art over the present application because it teaches that AMPA receptor potentiators, such as CX717 (aka BCM) are "effective for the treatment of impairment in memory or other *cognitive functions in general* particularly for the subject populations of humans and animals". Applicants respectfully submit that the Examiner has misunderstood the scope of the teachings of Rogers set forth in the FIELD OF THE INVENTION of Rogers and the Examiner's misunderstanding has formed the basis of her rejection.

When the Rogers prior art reference is examined and the FIELD OF THE INVENTION is scrutinized, it is clear to the routineer that there is absolutely no statement, nor even an implication, that the instant compounds would be effective to treat impaired memory or cognitive functions "in general". Quite the contrary, the inventors clearly limit the field of the invention by stating that the 'these brain networks are

involved in cognitive abilities related to memory impairment, such as is observed in a *variety of dementias*, and in imbalances in neuronal activity between different brain regions, as is suggested in *disorders such as schizophrenia*". Dementias and schizophrenia certainly do not extrapolate to "cognitive functions in general". Thus, Rogers is actually directed to a much less broad teaching and certainly there was no understanding from Rogers that the compounds which are disclosed therein were useful for memory impairment in general, but rather to memory impairment associated with dementia and disorders such as schizophrenia.

Indeed, prior to the presentation of the present invention, it was not generally understood in the art that memory impairment associated with chronic or acute sleep deprivation was related to neural receptors which are activated by AMPA receptor potentiators or Ampakines. Applicants note that it was the very discovery that memory impairment from acute and chronic sleep deprivation was associated with AMPA receptors that gave rise to the present invention. Indeed, many symptoms that a patient may present, require knowledge of the cause before the proper treatment (drug) can be selected. This was not known in the art and was certainly not known and taught in Rogers. This is especially true given the complexity of brain chemistry and relationship of that complexity to physiological manifestations in the form of brain function. In other words, without concrete evidence, it is virtually impossible to draw conclusions about chemical activity and brain function.

Thus, a fair reading of the Rogers reference imposes credible limitations on the scope of those teachings, and those teachings do not give rise to or suggest the presently claimed invention. It is respectfully submitted that the Examiner is engaging in an impermissible hindsight analysis in making her rejection of the present invention under 35 U.S.C. §103. It has long been established that the application of hindsight to an obviousness analysis is impermissible under the law. A long line of United States Supreme Court cases has set forth the precedent that a hindsight construction of an obviousness rejection is impermissible under the law. See, for example, *Graham v. John Deere Co.*, 383 U.S. 1 (1966), *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*,

220 U.S. 428 (1911) and *Loom Co. v. Higgins*, 105 U.S. 580 (1881), among numerous others.

Here, Applicants respectfully submit that the Examiner is engaging in an impermissible hindsight construction because she is imposing the teachings of the present invention on the Rogers prior art where no such teaching or suggestion exists. Indeed, Rogers is absolutely *silent* on cognitive deficiencies associated with acute and/or chronic sleep deprivation and for the reasons presented above, any teachings of Rogers is limited in scope and does not credibly suggest the present invention which is narrowly focused on a condition which occurs secondary to a natural process (sleep deprivation) which is not even *contemplated* by the prior art. Applicants note that one of the co-inventors of the Rogers prior art, Dr. Gary Rogers, also a co-inventor of the present application, has facilitated the filing of numerous patent applications throughout the world based upon the present invention. Applicants further note that many of the applications based upon the presently claimed invention have been allowed and/or issued based upon Dr. Rogers' view, in reading and understanding his own teachings in the Rogers prior art reference, that the present invention is patentable and is not previously taught, either by himself in his own references or in any other prior art of which he is aware. Accordingly, Applicants respectfully submit that the present invention is non-obvious and patentable over the cited prior art and respectfully request that the Examiner withdraw her rejection of the present invention as being obvious over Rogers.

For the above reasons, it is respectfully submitted that the claims of the present application is patentable over the cited art and Applicants respectfully request that the Examiner permit this application to proceed to allowance.

No fee is due for the presentation of the present amendment/response, inasmuch as a number of claims have been deleted from the present application and a single dependent claim has been added. The fees for a petition for an extension of time of two months and a request for continued examination (RCE) (\$535) is requested to be charged to the appropriate fee to Deposit Account 04-0838. Separately, Applicants petition for

C21-074US.prelim amendment 2-11  
Preliminary Amendment of February 2011  
S.N. 10/541,687

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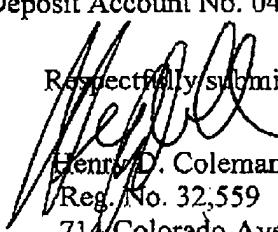
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suspension of action on the above-referenced application for 3 months under 37 C.F.R. 1.103(c). A fee of \$130 under 37 C.F.R. 1.17(i) is due and is authorized to be charged to Deposit Account 04-0838.

Small entity status continues to apply to the present application. Please charge any fee due or credit any overpayment made to Deposit Account No. 04-0838.

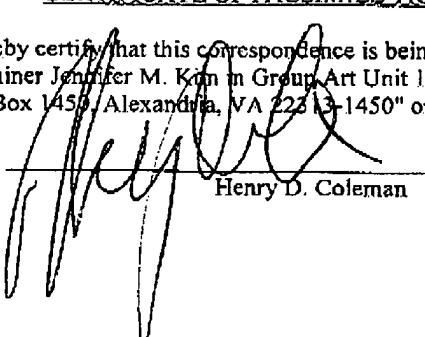
Respectfully submitted,

Dated: February 10, 2011

  
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being sent by facsimile transmission to Examiner Jennifer M. Kim in Group Art Unit 1628 of the United States Patent Office P.O.Box 1450, Alexandria, VA 22313-1450" on February 10, 2011.

  
Henry D. Coleman

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